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**STATE OF DELAWARE  
BOARD OF PHARMACY**

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<b>PUBLIC MEETING NOTICE:</b>	<b>BOARD OF PHARMACY</b>
<b>DATE AND TIME:</b>	<b>Wednesday, November 20, 2013</b>
<b>PLACE:</b>	Conference Room A, Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
<b>APPROVED:</b>	

**MEMBERS PRESENT**

Joli Martini, R.Ph., PharmD, Professional Member, President  
Kimberly Robbins, R.Ph, Professional Member, Vice President  
Tejal Patel, R.Ph, Professional Member  
Bonnie Wallner, R.Ph, Professional Member  
Matthew Maher, Public Member  
David W. Dryden, R.Ph., J.D., Executive Secretary

**MEMBERS ABSENT**

Sandra Zaragoza, R.Ph, Professional Member  
Susan Esposito, R.Ph, Professional Member  
Kenneth Sellers, Public Member  
Jay Galloway, Public Member

**DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT**

Eileen Kelly, Deputy Attorney General  
Theresa Newman, Administrative Specialist II  
Christine Mast, Administrative Specialist III  
Alicia Kluger, Pharmacist Compliance Officer

**ALSO PRESENT**

Sandra S. Robinson	Suzanne Raab-Long
Cheryl Heiks	Deborah Hamilton
Bhavin Patel	Gerald McGordy
Al Carter	Bryan Bornacelly
Olu Ifesonwya	Bill Harbester
Don Holst	Dipen Patel
Phil Anderson	

**CALL TO ORDER**

Ms. Martini called the meeting to order at 9:33a.m.

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### **REVIEW OF MINUTES**

A motion was made by Ms. Robbins, seconded by Mr. Maher, to approve the meeting minutes for October 16, 2013 as amended. The motion unanimously carried.

### **PRESIDENT'S REPORT**

Ms. Martini attended the Controlled Substance Committee meeting last month. She continues to work on collaborative care and would like to form a committee to meet prior to the upcoming holidays. Ms. Martini welcomed new board member Ms. Tejal Patel to the Board. Ms. Patel introduced herself and provided a brief description of her background in pharmacy and pharmacy management. Ms. Martini also welcomed new board professional member Susan Esposito to the board. Ms. Esposito was not in attendance at today's meeting.

### **UNFINISHED BUSINESS**

#### Complaint Status

13-03-11 – Assigned to Hearing Officer  
13-09-11 – Assigned to Hearing Officer  
13-12-11 – Forwarded to Office of Attorney General  
13-19-11 – Forwarded to Office of Attorney General  
13-07-12 – Closed  
13-09-12 – Assigned  
13-01-13 – Forwarded to Office of Attorney General  
13-02-13 – Assigned  
13-03-13 – Assigned  
13-04-13 – Forwarded to Office of Attorney General  
13-05-13 – Assigned  
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13-09-13 – Assigned  
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13-19-13 – Assigned  
13-20-13 – Assigned  
13-21-13 – Assigned  
13-22-13 – Assigned  
13-23-13 – Assigned  
13-24-13 – Assigned

#### Prescription Monitoring Program (PMP) Update

Ms. Nettesheim reported that the Delaware PMP has over Mr. Dryden presented a handout to the board titled "Delaware Prescription Monitoring Program Interstate Data Sharing". The handout outlined interstate data sharing between Connecticut, Indiana, and North Dakota as the first states sharing data with Delaware. Delaware expects that the listing of states sharing information will continue to grow quarterly. Anticipated access to adjacent state data sharing is as follows: New Jersey anticipates interstate data sharing capabilities by the end of 2014, Maryland PMP data is currently available to licensed practitioners with data sharing anticipated sometime in 2015, and Pennsylvania PMP data is currently restricted to Law Enforcement only. It will take some time for

adjacent states to begin sharing data due to statute and regulatory changes that are currently being addressed.

#### Collaborative Practice Review

Mr. Dryden will begin assembling interested individuals and organizations into a committee with an anticipated committee meeting prior to year end 2013.

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#### Discussion of Regulation 12.0 Health Care Facilities

Ms. Robinson and Ms. Kluger presented the board with updated rules for the board to consider. The board discussed and made some corrections to language and to numbering in 12.2.2. A motion was made by Ms. Wallner, seconded by Ms. Robbins, to approve as amended. The motion unanimously carried.

#### Discussion of Oxygen Bar

Mr. Dryden suggested writing a letter to the FDA, addressing the concerns of the board. The FDA believes there may not be any concerns due to concentration levels however; the FDA could not provide the levels of concentration that would be of concern. The FDA has stated that additives may be of concern. The USP defines concentration levels of 99 percent or above as medicinal and must be regulated. The board agreed that all medical claims should be discontinued. Mr. Dryden will attempt to attend the webinar for the FDA. This item was tabled until the next meeting for further review.

#### Review and Discussion of Consent Agreement

The Board tabled the Consent Agreement of Michelle Woods, pending a response from the DAG.

#### Walgreens Wellness Presentation

Mr. Al Carter of Walgreens addressed the board concerning previous claims regarding the Walgreens Well Experience pharmacy format. Mr. Carter sent a response letter outlining changes and improvements to the format. Mr. Carter vocalized that error rates with the new system have decreased compared to the traditional pharmacy setting. There will be a report coming from Senator Markee in support of the Well Experience “Change to Win” model. Delaware currently has 2 locations with the new “Change to Win” format.

#### Appointment of Sandy Robinson to PA Council

A motion was made by Mr. Maher, seconded by Ms. Wallner, to appoint Sandra Robinson to the PA Counsel retroactive to July 23, 2013. The motion unanimously carried.

#### Update: Pharmaceutical Compounding Issues

Mr. Dryden stated that there is a new federal pharmacy compounding law enacted. He stated that a committee meeting would need to be held to address the new federal statute and presented to the board.

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### **NEW BUSINESS**

#### Pharmacist and Intern Licensure Approval Ratifications

A motion was made by Ms. Robbins, seconded by Mr. Maher, s. Robbins, to ratify the approval of the Pharmacist applications of Desta Kamala, Jay Patel, Shannon Tryon, James Xu, Natalie Hemphill, Abduleslam Suleyman, Diane Pasco, Ogoosi, Johee Lee, Susan Sincavage, Jon

Wallner, Rina Kelley, Na'Teka Shelton, Chad Forinash, David Dinh, and Gary Sobocinski. TThe motion unanimously carried.

A motion was made by Ms. Robbins, seconded by Mr. Maher, to ratify the approval of the Intern Pharmacist application of Brittany Coleman. Viha Dave, Robert Wright, and Laura Wolfe. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A motion was made by Ms. Wallner, seconded by Mr. Maher to ratify the approval of the non-resident pharmacy applications of SimfaRose Pharmaceutical Specialty, Inc –FL, Town Total Health, LLC – NY, HealthScripts Specialty Pharmacy, LLC – TX, Pillpack, Inc. – NH, Parkway Pharmacy, LLC – NJ, The Medimix, LLC dba Medimix Specialty – FL, Marwood Low Cost Pharmacy, LLC – IN, Dalton Pharmacy – AL, Entireypets Pharmacy – CA, Burman's Apothecary, LLC – PA. Green Valley Drugs, Goot Nursing Home Pharmacy, Inc., Walgreen Co., Mead Square Pharmacy, Inc., Prescription Dynamics, Inc., Arrow Pharmacy Holdings, LLC, HomeChoice Partners, Inc., and Pharmaceutical Specialties, Inc. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A motion was made by Ms. Wallner, seconded by Mr. Maher, to ratify the approval of the wholesale distributor applications of Cardinal Health 200, LLC – TX, Cardinal Health 200, LLC – MS, Alcon Laboratories, Inc. – TX, DUSA Pharmaceuticals, Inc. – OH, Gulf South Medical Supply, Inc – FL, Grifols USA, LLC – CA, Cooper Surgical, Inc – CT, Diplomat Pharmacy Services – MI. DPT Laboratories, Ltd., Antigen Laboratories, Watson Pharma, Inc., Grifols USA, LLC, and Matheson Tri-Gas, Inc. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A motion was made by Ms. Wallner, seconded by Mr. Maher, to ratify the approval of the retail pharmacy application Delaware CVS Pharmacy, #10296, Delaware CVS Pharmacy #10222. The motion unanimously carried.

Medical Gas Dispensers

A motion was made by Ms. Wallner, seconded by Mr. Maher, to ratify the approval of the Medical Gas Dispensers application Americoast Delaware, LLC, Medtix, LLC Millsboro, Medtix, LLC Lewes, Medtix, LLC Milford. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted a PIC interview for Dipen Patel – Shayona Pharmacy.

A motion was made by Ms. Wallner, seconded by Mr. Maher, to amend the agenda to add an additional PIC interview to the agenda: Bhavin Patel – Walmart Wilmington, DE. The motion unanimously carried.

Ms. Robbins conducted a PIC interview for Bhavin Patel – Walmart Wilmington, DE.

Consultant Pharmacist Interview

N/A

Review of Applications by DAG

Board DAG Eileen Kelly provided the board guidance on the following disciplinary records for applications received followed by the board ruling:

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**Harlan Smith** - Pharmacist - A motion was made by Ms. Wallner, seconded by Ms. Robbins, to approve the application.

**Lawrence Lubonski** - Pharmacist - A motion was made by Mr. Maher, seconded by Ms. Wallner, to Propose to Deny the application.

**Ronald Sansone** - Pharmacist - A motion was made by Ms. Robbins, seconded by Ms. Wallner, to Propose to Deny the application.

**Melissa Miller-Beatty** - Pharmacist - A motion was made by Ms. Robbins, seconded by Ms. Wallner, to approve the application.  
by Walmart Pharmacy #10-5436.

Ms. Robbins conducted a PIC interview for Lisa Skedzielewski. She is employed by Walgreens Pharmacy #12040.

#### Deliberation of Rules and Regulations Revisions

Hearing was held on October 16, 2013. The definition of compounding was revised and other changes were made to the rules and regulations. Deliberations began at 11:16 a.m. Ms. Kelly stated the deliberations are to discuss the adoption of amendments to the Rules and Regulations which were published on April 1, 2013 in the Registrar. The Board did not receive comments thru testimony or in writing by the October 31, 2013 deadline, the board deliberated and a motion was made by Ms. Martini, seconded by Ms. Wallner, to approve the amendments as published. The motion unanimously carried. Deliberations ended at 11:20am, the orders were signed by the board.

#### Consultant Pharmacist Interview

Ms. Robbins conducted a Consultant Pharmacist interview for Joshua Coffield. He is employed by Cardinal Health at the DE Hospital for the Chronically Ill in Smyrna.

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#### Collaborative Practice Review

Julie Wenger, from the National Association Chain Drug Stores and Kevin Gorslive, from Rite Aid, discussed collaborative agreement practices. Ms. Wegner read a letter to the board of their stating their proposal. Ms. Kelly will review the issue to insure whether the change would need to be a statutory change or a regulation change. Mr. Dryden will also gather items that were presented previously regarding this matter.

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#### Board Election of Officers

A motion was made by Ms. Robinson, seconded by Mr. Galloway to elect Joli Martini as the Board's President and Kimberly Robbins as the Vice President. The motion unanimously carried.

#### **COMMITTEE REPORTS**

**Legislative – Sandy Robinson, Jay Galloway, Kim Robbins and David Dryden**

None

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#### **Continuing Education – Joli Martini and Sandy Robinson:**

David Dryden – NASCSA Annual Conference Program submitted for approval, 11 Continuing Education credits approved. A motion was made by Ms. Robbins, seconded by Ms. Wallner, to approve the continuing education credits. The motion unanimously carried.

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Ms. Martini advised that ACPE, has a suffix of HO5, to qualify as a medication safety/ medication error continued education credit. The Board will review each course taken on a case by case basis to accept safety/ medication error CE, which does not have a HO5 suffix on the certificate. The CE will be monitored by the random audit conducted by the Division of Professional Regulation.

Those of which who attended the Attorney General Summit did not receive a number on the certificate for proof of continued education. The Board advised for those who attended, keep the

record of the certificate, and if they are chosen for audit, the continued education certificate will provide substantial proof of completion.

**Consumer Affairs – Matthew Maher and Jay Galloway:**

NoneNo report.

**Professional Liaisons – Sandra Zaragoza:**

None

Ms. Robinson reported she has not received any information for the program DHSP but when she receives the information she will report.

Ms. Robinson attended the DPS meeting. A board report was submitted by Ms. Robinson.

**Controlled Substance Liaisons – Jay Galloway and David Dryden:**

Mr. Simon stated the next meeting is scheduled for August 28, 2013.

Mr. Dryden reported that the Drug Disposal on October 26<sup>th</sup> that had resulted in 5258 pounds of expired medications collected. This was the third highest collection of record.

**COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS**

**USP 795 & 797 Committee – Sandy Robinson, Alicia Kluger, Brenda Pavlic, Sandra Zaragoza, Hooshang Shanehsaz, Calvin Freedman and David Dryden:**

Mr. Dryden expressed that another committee meeting would be required to determine the recommendations.

The Board is waiting for the FDA amendments.

**Immunization/Pen Needle Committee – Howard Simon, Kim Robbins, Mark Freebery and David Dryden:**

No report.

**Pharmacy Technician Licensure Committee – Matt Maher, Sandy Robinson, Kim Robbins, Kevin Musto, Maryanne Holzapfel and David Dryden:**

Ms. Robbins reported that Mr. Collins had attended the previous committee meeting and expressed that the committee should not focus solely on the required resources of this licensure and should focus on the task in completing the goals and requirements for licensure. The committee name has been amended to be a licensure committee instead of registration. We will be doing a complete review of Regulation 9 to add in the licensing of the Pharmacy Technician. We have assigned a member to bring in the regulations from Maryland and looking for the PCTB listing of all technicians in the state. The committee supports the needs of resources outside of the pharmacy being utilized during times of need. The committee is still soliciting Technicians to become part of the committee. Ms. Robbins also stated that she would be attending the next DPS meeting in early December, she will report back during the next meeting.

The next meeting will be held on August 21, 2013 at 11:00 a.m.

**BOARD CORRESPONDENCE**

NABP – Dated November 1, 2013 “Sellers of Unapproved Drugs Proliferate Online, Posing a Serious Threat to Global Public Health”

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NABP – Dated October 30, 2013 “CPE Monitor Reaches a Milestone with Over Five Million CPE Activities Tracked”

NABP – Dated October 9, 2013 “Prescription Drug Supply Chain at Risk for Diversion Schemes and Counterfeit Drug Distribution”

NASCSA – this year’s focus is telemedicine.

2013 NABP Program Review and Training Session

Mr. Dryden read the correspondence from NABP, dated June 13, 2013, regarding the upcoming NABP training session. Two representatives will attend the meeting to gain additional knowledge of products and features NABP offers to enhance the internal process of applications.

Mr. Dryden advised at the NABP annual meeting, delegates from the Board of Pharmacy, voted to pass resolution to 109-1-13, Pharmacy Compounding and Sterile Products, recognizing the need to protect the public’s health and safety.

APN Consensus Model Bill

Mr. Dryden advised the Board that the Board of Medical Practice sent a letter to the Board of Nursing to advise they do not support the nursing endeavor.

**EXECUTIVE SECRETARY AND INSPECTION REPORT - David Dryden, Samantha Nettesheim and Alicia Kluger**

Mr. Dryden stated he attended the District 2 and NASCSA conferences. He communicated that there was a great deal of relevant information regarding Telemedicine and the increase in diversion communicated during the meetings.

Ms. Kluger reported the following inspections and activities were completed during the last 30 days:

- 2 Pharmacy opening inspections (chain)
- 1 Nursing Home Inspections and pharmacy provider
- 1 Practitioner Inspection Pharmacy investigation
- 1 Follow up to a complaint – Nursing Home

There were also multiple drop-ins to evaluate prescription compliance and concerns.

During the last 30 days there were following losses of controlled substances reported:

- Rite Aid #814 – 10/26/2013
- Rite Aid #3748 – 10/30/2013

Pharmacist in Charge Self Inspection Report – Recommended Drugs for Audit 2014

- Hydrocodone/APAP 5/500 tabs (CIII)
- Amphetamine sulfate 30 mg (CII)
- Carisopodol 350 mg tabs (CIV)
- Oxycodone 15 mg tabs (CII)

Ms. Kluger stated the discrepancy parameters will be as follows: ***“If a discrepancy is greater than 0.2% for schedule II medications or 3% for schedule III-V medications submit a report to the Board within 30 days with an explanation”.***

**The following inspections and activities were completed during the last 30 days:**

- 3 routine pharmacy inspections
- 2 pharmacy opening inspection
- 1 pharmacy remodel
- Inspected random inspection of Treatment Centers

During the last 30 days there were no theft/loss or robberies were reported.

Ms. Kluger reported we have received a 38% response to the Delaware survey which was to be completed by all resident and non-resident pharmacies. Out of the response that was received 9 out of 13 licensed hospitals, compound sterile products; out of 207 active licensed retail stores, 8 have reported they also compound sterile products; and out of 540 active Non-Resident Pharmacies, 56 responded thus far to compounding sterile products.

#### **NEWSLETTER UPDATES**

Mr. Dryden reported that the 4<sup>th</sup> Quarter Newsletter had been released electronically. He stated that the newsletter included the schedule of 2014 board meetings, introduction of the four new board members and included an article on “Abuse and Dependency” of controlled substances. No report.

#### **OTHER BUSINESS BEFORE THE BOARD**

Ms. Wallner advised that the USP’s definition for the medical concentration of Oxygen is 99%. Ms. Martini thanked Alicia Kluger for her service to the board.

Ms. Robinson, advised the Board that a Deputy Attorney General’s bill was created to record deliberations. The concern is regarding violation of HIPPA laws regarding the Board discussing matters within the board meeting. Ms. Kelly will look further into the matter.

#### **PUBLIC COMMENTS**

Ms. Sandy Robinson suggested that facilities listed on the boards ratification listing include information regarding sterile compounding.

Mr. Bill Harvester thanked Alicia Kluger for her service and assistance with the rules and regulations. He asked the board for an effective date for the amended rules and regulations, the effective date will be December 11, 2013.

None.

#### **NEXT SCHEDULED MEETING**

The next meeting is scheduled for January 15, 2014. August 21 Conference Room A

#### **ADJOURNMENT**

There being no other business before the Board, a motion was made by Ms. Wallner. Martini, seconded by Ms. Robbinss. Robinson, to adjourn the meeting. The meeting was adjourned at 11:45 0:55am.

Respectfully submitted,



Christine Mast  
Administrative Specialist III